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GSK receives FDA nod for its triple drug inhaler

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The approval will help GSK strengthen its respiratory drug pipeline, despite falling sales of older drug Advair

Bringing in much needed relief for patients suffering from Chronic Obstructive Pulmonary Disorder (COPD), the US FDA has granted approval to GSK's triple therapy inhaler Trelegy Ellipta. The approval will help GSK strengthen its respiratory drug pipeline, despite falling sales of older drug Advair.

Trelegy Ellipta combines three active molecules - fluticasone furoate, umeclidinium, vilanterol (FF/UMEC/VI), found in Breo Ellipta and Incruse Ellipta - in the same inhaler, and is the first once-daily triple medicine for COPD to hit the market.

GlaxoSmithKline and Innoviva announced the approval stating that the new inhaler will help in providing relief to millions of patients. Eric Dube, SVP & Head, GSK Global Respiratory Franchise, said, "COPD is a progressive disease that can worsen over time, and represents a significant burden to patients and healthcare systems. The approval of Trelegy Ellipta, and the addition of a once-daily single inhaler triple therapy to our portfolio of respiratory medicines, is an important milestone for GSK that builds on our long heritage in this area."

"This approval represents a significant therapeutic convenience for those appropriate patients already on Breo Ellipta, that require additional bronchodilation or for those patients already on a combination of Breo Ellipta and Incruse Ellipta, added, Mike Aguiar, CEO of Innoviva, Inc. " Trelegy Ellipta is the latest development in our collaboration with GSK and is testament to our ongoing efforts to advance respiratory medicine."

The decision follows a recent marketing recommendation by the European Medicines Agency's CHMP, based on data from the FULFIL study showing statistically significant improvements with the triple therapy compared with the dual therapy Symbicort Turbohaler (budesonide/formoterol) in both lung function, as measured by trough FEV1 (+171 mL), and health-related quality of life, as measured by the St. George's Respiratory Questionnaire (-6.6 versus -4.3, respectively).

Following this approval by the FDA, Trelegy Ellipta will be available in the US shortly.

Regulatory applications have been submitted and are undergoing assessment in a number of other countries, including the European Union, Australia and Canada.